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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/890,652	11/27/2001	Bernard Klein	USB 98BEIDMPOI	5268

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EXAMINER

BELYAVSKIY, MICHAEL A

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 07/30/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/890,652

Applicant(s)

KLEIN ET AL.

Examiner

Michail A Belyavskiy

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 11/27/01 and 17 May 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) 7-12 and 16 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 2,4,5 and 17 is/are allowed.
- 6) ☒ Claim(s) 1,3,6, 13-15 and 18-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Filed by Paper No(s) 08/03/01
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

1. Applicant's amendment, filed 5/17/02 (Paper No.7), is acknowledged.

Claims 1-19 are pending.

Applicant's election with traverse of Group II (claims 2,4, 5, 6 and 17-19) is acknowledged. The traversal is on the grounds that "lack of unity determination requires explanation why each group lacks unity with each other group and that International Search Report finds no lack of unity of invention".

Upon further consideration, Groups I and II have been re-joined. The restriction between Groups III to VII is still proper.

CFR 1.475 (a) indicates that a national stage application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept. Where a group of inventions is claimed in an application, the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art. CFR 1.475(e) indicates that the determination whether a group of inventions is so linked as to form a single general inventive concept shall be made without regard to whether the inventions are claimed in separate claims or as alternatives within a single claim (MPEP R-90 -- R-91 and 1893.03(d)).

In the previous Office Action it was stated : As was found in the International Search Report, the Invention Group I was found to have no special technical feature that defined the contribution over the prior art of Srour (US Patent No 5,672,346) (see entire document).

Srour discloses human pluripotent hematopoietic stem cell enriched composition and their capacity to differentiate into members of erythroid, myeloid and megakaryocyte cell lineages. By grafting human hematopoietic cells in a mammal, peripheral blood cell compositions containing CD14+ cells (macrophages) can be obtained.

Since Applicant's inventions do not contribute a special technical feature when viewed over the prior art they do not have a single general inventive concept and so lack unity of invention.

The requirement is still deemed proper and is therefore made FINAL.

Claims 7-12 and 16 are withdrawn from further consideration by the Examiner, 37 C.F.R. § 1.142(b) as being drawn to a nonelected invention.

Claims 1-6, 13-15 and 17-19 are under consideration in the instant application.

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2. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention *to which the claims are directed*.

3. The drawings are objected to because of the errors listed on the PTO-948; therefore, the drawings fail to comply with 37 CFR 1.84. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance. Please see the attachment to the PTO-948.

Correction of Informalities -- 37 CFR 1.85

New corrected drawings must be filed with the changes incorporated therein. Identifying indicia, if provided, should include the title of the invention, inventor's name, and application number, or docket number (if any) if an application number has not been assigned to the application. If this information is provided, it must be placed on the front of each sheet and centered within the top margin. If corrected drawings are required in a Notice of Allowability (PTOL-37), the new drawings **MUST** be filed within the **THREE MONTH** shortened statutory period set for reply in the "Notice of Allowability." Extensions of time may NOT be obtained under the provisions of 37 CFR 1.136 for filing the corrected drawings after the mailing of a Notice of Allowability. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.

Corrections other than Informalities Noted by Draftsperson on form PTO-948.

All changes to the drawings, other than informalities noted by the Draftsperson, **MUST** be made in the same manner as above except that, normally, a highlighted (preferably red ink) sketch of the changes to be incorporated into the new drawings **MUST** be approved by the examiner before the application will be allowed. No changes will be permitted to be made, other than correction of informalities, unless the examiner has approved the proposed changes.

Timing of Corrections

Applicant is required to submit acceptable corrected drawings within the time period set in the Office action. See 37 CFR 1.85(a). Failure to take corrective action within the set period will result in **ABANDONMENT** of the application.

4. The disclosure is objected to because of the following informalities: the words "myeloid" and "erythroid" in claims and specification are misspelled.
Appropriate correction is required.

5. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which Applicant may become aware in the specification.

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5. The following is a quotation of the second paragraph of 35 U.S.C. 112.

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 6, 13-15 and 18 -19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. Dependent claims 6 recites "the lymphocytes". There is insufficient antecedent basis for this limitation in the claims, since base Claim 2 does not recite lymphocytes. Applicant should amend article "the" to the article "a".

B. Claims 14 and 18 improperly recite "the pharmaceutical composition". Applicant should amend article "the" to the article "a". In addition, claims 14 and 18 are indefinite in the recitation of "pharmaceutical composition". Minimally, a carrier should be recited.

C. Claim 13 recites "cell composition". It is improper claim language since an article is missing. Applicant should insert an article "A".

D. Claims 15 and 19 are indefinite for being in improper format. The word "and" should be inserted on the penultimate line.

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1, 3 and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Yamamoto (US Patent No 5326749) (see entire document).

Yamamoto teaches a cell composition containing macrophages and T lymphocytes (Column 1 line43). Yamamoto further teaches that incubation of macrophages with lysophospholipides or alkylglycerols greatly enhanced anti-infectious and hematopoietic activity of macrophages (column 1 lines 44-65).

Claim 1 is included, because the term "containing" recited in claim 1 line 1 is open-ended. It would open up the claimed composition to include the reference T lymphocytes.

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Claim 3 is included because the referenced peritoneal cells composition (column 8, line 63) would inherently contains T lymphocytes in a ration of about 10-60% with respect to total number of cells.

Claim 14 is included because the claimed functional limitation would be inherent properties of the referenced cell composition. A composition is a composition irrespective of what its intended use. The term "pharmaceutical composition" carries little patentable weight in the absence of evidence of structural difference.

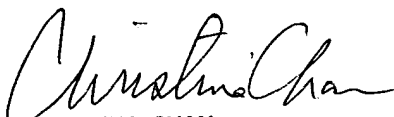
The reference teaching anticipate the claimed invention.

9. No rejections on Claims 2, 4,5 and 17.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michail Belyavskyi whose telephone number is (703) 308-4232. The examiner can normally be reached Monday through Friday from 9:00 AM to 5:30 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Michail Belyavskyi, Ph.D.
Patent Examiner
Technology Center 1600
July 18, 2002


CHRISTINA CHAN
SUPERVISORY PATENT EXAMINER
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